As ranking member of the Committee of Foreign Affairs' Subcommittee on Asia, the Pacific, and Nonproliferation, I strongly support this legislation and I commend both the chairman of the committee, Mr. MEEKS, and the ranking member, Mr. MCCAUL, for their leadership on this particular issue.

They have been stressing this. They have been pushing this. They have been speaking out on this for quite some time now, and I am very pleased to see this come before the floor today. It is far beyond the time that action needs to be taken on this.

Mr. Speaker, the consistent undermining of human rights, perhaps the Chinese Communist Party's most fundamental challenge to the free world. China's totalitarian government, they have no use for human rights. Their bloody history demonstrates that. Relative to political freedom in China, one sees abuses from Tiananmen Square to Hong Kong. Freedom of speech? The great firewall shuts that down. Freedom of religion? The CCP, the Chinese Communist Party, persecutes Christians; they persecute the Falun Gong; they persecute Tibetan Buddhists; and they even want to dictate who the next Dalai Lama will be.

And the Chinese Communist Party has taken this campaign to a whole new level in Xinjiang where the Uyghurs are subject to forced labor, to torture, to sexual abuse, to religious persecution, and to onerous restrictions in every facet of their lives.

Over a million people, the vast majority of them Uyghurs, are in concentration camps today currently. While we are here, they are in concentration camps in China. The hallmark of genocide is the intent to destroy, to eliminate an entire people, and that intent is clear here. The Chinese Communist Party is snatching Uyghur children from their parents, imposing severe birth quotas on Uyghurs. They are conducting forced abortions. They are sterilizing a sizable percentage of the population against their will, and up to 80 percent in some areas of Xinjiang forced sterilization is occurring right now.

As a result of all this, the birth rate in Xinjiang fell by 24 percent—one out of four—in 2019 alone. This is genocide, and it is high time that the world got serious with the PRC, the People's Republic of China, about what they are doing to the Uyghurs. They have been doing it to a whole range of groups for a long time, but it is particularly brutal when it comes to the Uyghurs, and American businesses have to make sure that they are not profiting by this essentially slave labor, whatever businesses those are.

So there are things that we can do here in the United States but, ultimately, it is up to the PRC and it is up to the world to shine a light on this because this is happening right now. A million people or so are in these gulags right now.

Mr. Speaker, I again thank our leadership, and this is bipartisan leadership. It is Republicans and Democrats actually working together on this, and it is good to see that happen.

So again, I thank Mr. MEEKS and Mr. MCCAUL for doing this.

Mr. MEEKS. Mr. Speaker, I reserve the balance of my time.

Mr. MCCAUL. Mr. Speaker, I am prepared to close, and I yield myself such time as I may consume.

Mr. Speaker, let me say in closing, I again thank Chairman MEEKS, my friend, who has been in strong support of this legislation. We pride our committee in doing what is right by the country. We try to take the politics out of it as much as we can. And as Eliot Engel often said, it stops at the water's edge, and this is no exception.

Mr. Speaker, this is a historic day. Congress is rarely in vote or declared genocide on another people, but it is very appropriate today to do so. And the international community is watching, and China is watching this right now. They are watching this on C–SPAN, and the world knows that the United States stands for higher moral values, and we stand for human rights.

And that is why this bill was introduced, and the lives of over a million people depend on it. Think about that. A million people in internment camps, concentration camps, being exterminated, depend on this legislation. We pass a lot of things in this Congress but it is very rare you can pass something like this that condemns this kind of moral atrocity and call it to the world so the entire world can see it for themselves what is, in fact, happening. And when Congress speaks, the world does listen. And when we speak as Americans in this Chamber, not as partisan politicians, they listen. And I know they are listening today.

Mr. Speaker, I yield back the balance of my time.

Mr. MEEKS. Mr. Speaker, I yield myself the balance of my time.

Mr. Speaker, I, too, thank Mr. MCCAUL for his leadership. It is my pleasure to work with him on this bill to get this to the floor and to pass it on this floor, the people's House, in a bipartisan way, sending a strong message together. That is what this does. So I thank him for his friendship, and I thank him for standing up, as he does, and working together in a bipartisan way.

Mr. Speaker, H. Res. 317, condemning the ongoing genocide and crimes against humanity being committed against the Uyghurs and members of other religious and ethnic minority groups by the People's Republic of China is critical to demonstrating to those suffering in Xinjiang that they haven't been forsaken. And to the government of Beijing, we will speak out when it tramples the universal rights that every human being deserves.

It gives me hope that we are not the first parliamentary body that has deemed the PRC's action in Xinjiang a genocide. The parliaments of the U.K., of Canada, of Lithuania, among others, have already taken the right stand. We must support them. We must work with them and multilateral groups. We must encourage other nations and other people to speak out. But I am proud we are speaking out here today in the United States Congress, in the people's House. We will not be silent.

Mr. Speaker, I hope that all my colleagues will join me in supporting this resolution, and I yield back the balance of my time.

Mr. PFLUGER. Mr. Speaker, I rise today to shed light on the horrific genocide that Communist China is committing against Uyghurs and other ethnic and religious minorities.

Right now, over one million Uyghurs are enslaved by the People's Republic of China in the Xinjiang region, where they are subjected to horrific human rights atrocities like forced sterilization and abortions, slave labor, and even execution.

Communist China is actively attempting to wipe out an entire people group, and the United States must not allow it.

A few months ago, I—and other members of the Foreign Affairs Committee—heard directly from Ms. Tursunay Ziyawudun, a survivor of a CCP's concentration camp. She told us harrowing stories of the horrific atrocities she suffered through.

It was absolutely heartbreaking. I cannot imagine my wife or daughters being subjected to an environment like that.

Today's resolution sends the message directly from the United States to the Chinese government, that they must immediately end their ongoing crimes.

I applaud Republican Leader MCCAUL and Chairman MEEKS for their work to address this heartbreaking atrocity.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from New York (Mr. MEEKS) that the House suspend the rules and agree to the resolution, H. Res. 317, as amended.

The question was taken.

The SPEAKER pro tempore. In the opinion of the Chair, two-thirds being in the affirmative, the ayes have it.

Mr. CLYDE. Mr. Speaker, on that I demand the yeas and nays.

The SPEAKER pro tempore. Pursuant to section 3(s) of House Resolution 8, the yeas and nays are ordered.

Pursuant to clause 8 of rule XX, further proceedings on this motion are postponed.

ACCELERATING ACCESS TO CRITICAL THERAPIES FOR ALS ACT

Mr. PALLONE. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 3537) to direct the Secretary of Health and Human Services to support research on, and expanded access to, investigational drugs for amyotrophic lateral sclerosis, and for other purposes, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 3537

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Accelerating Access to Critical Therapies for ALS Act''.

SEC. 2. GRANTS FOR RESEARCH ON THERAPIES FOR ALS.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall award grants to participating entities for purposes of scientific research utilizing data from expanded access to investigational drugs for individuals who are not otherwise eligible for clinical trials for the prevention, diagnosis, mitigation, treatment, or cure of amyotrophic lateral sclerosis. In the case of a participating entity seeking such a grant, an expanded access request must be submitted, and allowed to proceed by the Secretary, under section 561 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb) and part 312 of title 21, Code of Federal Regulations (or any successor regulations), before the application for such grant is submitted.

(b) APPLICATION.—

(1) IN GENERAL.—A participating entity seeking a grant under this section shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary shall specify.

(2) USE OF DATA.—An application submitted under paragraph (1) shall include a description of how data generated through an expanded access request under section 561 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb) with respect to the investigational drug involved will be used to support research or development related to the prevention, diagnosis, mitigation, treatment, or cure of amyotrophic lateral sclerosis.

(3) NONINTERFERENCE WITH CLINICAL TRIALS.—An application submitted under paragraph (1) shall include a description of how the proposed expanded access program will be designed so as not to interfere with patient enrollment in ongoing clinical trials for investigational therapies for the prevention, diagnosis, mitigation, treatment, or cure of amyotrophic lateral sclerosis.

(c) SELECTION.—Consistent with sections 406 and 492 of the Public Health Service Act (42 U.S.C. 284a, 289a), the Secretary shall, in determining whether to award a grant under this section, confirm that—

(1) such grant will be used to support a scientific research objective relating to the prevention, diagnosis, mitigation, treatment, or cure of amyotrophic lateral sclerosis (as described in subsection (a));

(2) such grant shall not have the effect of diminishing eligibility for, or impeding enrollment of, ongoing clinical trials for the prevention, diagnosis, mitigation, treatment, or cure of amyotrophic lateral sclerosis by determining that individuals who receive expanded access to investigational drugs through such a grant are not eligible for enrollment in—

(A) ongoing clinical trials that are registered on ClinicalTrials.gov (or successor website), with respect to a drug for the prevention, diagnosis, mitigation, treatment, or cure of amyotrophic lateral sclerosis; or

(B) clinical trials for the prevention, diagnosis, mitigation, treatment, or cure of amyotrophic lateral sclerosis for which an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) has been granted by the Food and Drug Administration and which are expected to begin enrollment within one year; and

(3) the resulting project funded by such grant will allow for equitable access to investigational drugs by minority and underserved populations.

(d) USE OF FUNDS.—A participating entity shall use funds received through the grant—

(1) to pay the manufacturer or sponsor for the direct costs of the investigational drug, as authorized under section 312.8(d) of title 21, Code of Federal Regulations (or successor regulations), to prevent, diagnose, mitigate, treat, or cure amyotrophic lateral sclerosis that is the subject of an expanded access request described in subsection (a), if such costs are justified as part of peer review of the grant;

(2) for the entity's direct costs incurred in providing such drug consistent with the research mission of the grant; or

(3) for the direct and indirect costs of the entity in conducting research with respect to such drug.

(e) DEFINITIONS.—In this section:

(1) The term ''participating entity'' means a participating clinical trial site or sites sponsored by a small business concern (as defined in section 3(a) of the Small Business Act (15 U.S.C. 632(a))) that is the sponsor of a drug that is the subject of an investigational new drug application under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) to prevent, diagnose, mitigate, treat, or cure amyotrophic lateral sclerosis.

(2) The term ''participating clinical trial'' means a phase 3 clinical trial conducted pursuant to an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) to investigate a drug intended to prevent, diagnose, mitigate, treat, or cure amyotrophic lateral sclerosis.

(3) The term ''participating clinical trial site'' means a health care facility, or network of facilities, at which patients participating in a participating clinical trial receive an investigational drug through such trial.

(f) SUNSET.—The Secretary may not award grants under this section on or after September 30, 2026.

SEC. 3. HHS PUBLIC-PRIVATE PARTNERSHIP FOR RARE NEURODEGENERATIVE DISEASES.

(a) ESTABLISHMENT.—Not later than one year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall establish and implement a Public-Private Partnership for Neurodegenerative Diseases between the National Institutes of Health, the Food and Drug Administration, and one or more eligible entities (to be known and referred to in this section as the ''Partnership'') through cooperative agreements, contracts, or other appropriate mechanisms with such eligible entities, for the purpose of advancing the understanding of neurodegenerative diseases and fostering the development of treatments for amytrophic lateral sclerosis and other rare neurodegenerative diseases. The Partnership shall—

(1) establish partnerships and consortia with other public and private entities and individuals with expertise in amyotrophic lateral sclerosis and other rare neurodegenerative diseases for the purposes described in this subsection;

(2) focus on advancing regulatory science and scientific research that will support and accelerate the development and review of drugs for patients with amyotrophic lateral sclerosis and other rare neurodegenerative diseases; and

(3) foster the development of effective drugs that improve the lives of people that suffer from amyotrophic lateral sclerosis and other rare neurodegenerative diseases.

(b) ELIGIBLE ENTITY.—In this section, the term ''eligible entity'' means an entity that—

(1) is—

(A) an institution of higher education (as such term is defined in section 1001 of the Higher Education Act of 1965 (20 U.S.C. 1001)) or a consortium of such institutions; or

(B) an organization described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from tax under subsection (a) of such section;

(2) has experienced personnel with clinical and other technical expertise in the field of biomedical sciences and demonstrated connection to the patient population;

(3) demonstrates to the Secretary's satisfaction that the entity is capable of identifying and establishing collaborations between public and private entities and individuals with expertise in neurodegenerative diseases, including patients, in order to facilitate—

(A) development and critical evaluation of tools, methods, and processes—

(i) to characterize neurodegenerative diseases and their natural history;

(ii) to identify molecular targets for neurodegenerative diseases; and

(iii) to increase efficiency, predictability, and productivity of clinical development of therapies, including advancement of rational therapeutic development and establishment of clinical trial networks; and

(B) securing funding for the Partnership from Federal and non-Federal governmental sources, foundations, and private individuals; and

(4) provides an assurance that the entity will not accept funding for a Partnership project from any organization that manufactures or distributes products regulated by the Food and Drug Administration unless the entity provides assurances in its agreement with the Secretary that the results of the project will not be influenced by any source of funding.

(c) GIFTS.—

(1) IN GENERAL.—The Partnership may solicit and accept gifts, grants, and other donations, establish accounts, and invest and expend funds in support of basic research and research associated with phase 3 clinical trials conducted with respect to investigational drugs that are the subjects of expanded access requests under section 561 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb).

(2) USE.—In addition to any amounts appropriated for purposes of carrying out this section, the Partnership may use, without further appropriation, any funds derived from a gift, grant, or other donation accepted pursuant to paragraph (1).

SEC. 4. ALS AND OTHER RARE NEURODEGENERATIVE DISEASE ACTION PLAN.

(a) IN GENERAL.—Not later than 6 months after the date of enactment of this Act, the Commissioner of Food and Drugs shall publish on the website of the Food and Drug Administration an action plan describing actions the Food and Drug Administration intends to take during the 5-year period following publication of the plan with respect to program enhancements, policy development, regulatory science initiatives, and other appropriate initiatives to—

(1) foster the development of safe and effective drugs that improve or extend, or both, the lives of people living with amyotrophic lateral sclerosis and other rare neurodegenerative diseases; and

(2) facilitate access to investigational drugs for amyotrophic lateral sclerosis and other rare neurodegenerative diseases.

(b) CONTENTS.—The initial action plan published under subsection (a) shall—

(1) identify appropriate representation from within the Food and Drug Administration to be responsible for implementation of such action plan;

(2) include elements to facilitate—

(A) interactions and collaboration between the Food and Drug Administration, including the review centers thereof, and stakeholders including patients, sponsors, and the external biomedical research community;

(B) consideration of cross-cutting clinical and regulatory policy issues, including consistency of regulatory advice and decisionmaking;

(C) identification of key regulatory science and policy issues critical to advancing development of safe and effective drugs; and

(D) enhancement of collaboration and engagement of the relevant centers and offices of the Food and Drug Administration with other operating divisions within the Department of Health and Human Services, the Partnership, and the broader neurodegenerative disease community; and

(3) be subject to revision, as determined appropriate by the Secretary of Health and Human Services.

SEC. 5. FDA RARE NEURODEGENERATIVE DISEASE GRANT PROGRAM.

The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall award grants and contracts to public and private entities to cover the costs of research on, and development of interventions intended to prevent, diagnose, mitigate, treat, or cure, amyotrophic lateral sclerosis and other rare neurodegenerative diseases in adults and children, including costs incurred with respect to the development and critical evaluation of tools, methods, and processes—

(1) to characterize such neurodegenerative diseases and their natural history;

(2) to identify molecular targets for such neurodegenerative diseases; and

(3) to increase efficiency and productivity of clinical development of therapies, including through—

(A) the use of master protocols and adaptive and add-on clinical trial designs; and

(B) efforts to establish new or leverage existing clinical trial networks.

SEC. 6. GAO REPORT.

Not later than 4 years after the date of the enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report containing—

(1) with respect to grants awarded under the program established under section 2—

(A) an analysis of what is known about the impact of such grants on research or development related to the prevention, diagnosis, mitigation, treatment, or cure of amyotrophic lateral sclerosis; and

(B) data concerning such grants, including—

(i) the number of grants awarded;

(ii) the participating entities to whom grants were awarded;

(iii) the value of each such grant;

(iv) a description of the research each such grant was used to further;

(v) the number of patients who received expanded access to an investigational drug to prevent, diagnose, mitigate, treat, or cure amyotrophic lateral sclerosis under each grant;

(vi) whether the investigational drug that was the subject of such a grant was approved by the Food and Drug Administration; and

(vii) the average number of days between when a grant application is submitted and when a grant is awarded; and

(2) with respect to grants awarded under the program established under section 5—

(A) an analysis of what is known about the impact of such grants on research or development related to the prevention, diagnosis, mitigation, treatment, or cure of amyotrophic lateral sclerosis;

(B) an analysis of what is known about how such grants increased efficiency and productivity of the clinical development of therapies, including through the use of clinical trials that operated with common master protocols, or had adaptive or add-on clinical trial designs; and

(C) data concerning such grants, including—

(i) the number of grants awarded;

(ii) the participating entities to whom grants were awarded;

(iii) the value of each such grant;

(iv) a description of the research each such grant was used to further; and

(v) whether the investigational drug that was the subject of such a grant received approval by the Food and Drug Administration.

SEC. 7. AUTHORIZATION OF APPROPRIATIONS.

For purposes of carrying out this Act, there are authorized to be appropriated $100,000,000 for each of fiscal years 2022 through 2026.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from New Jersey (Mr. PALLONE) and the gentleman from Kentucky (Mr. GUTHRIE) each will control 20 minutes.

The Chair recognizes the gentleman from New Jersey.

GENERAL LEAVE

Mr. PALLONE. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days in which to revise and extend their remarks and include extraneous material on H.R. 3537.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from New Jersey?

There was no objection.

Mr. PALLONE. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, in July, the Committee on Energy and Commerce held a hearing to learn about the challenges associated with finding treatments for neurodegenerative diseases, including ALS.

We heard from the lead scientist from the National Institutes of Health and the Food and Drug Administration, and researchers at top universities, who discussed the difficulties scientists have had in understanding the complexities of the disease and developing biomarkers, a critical tool for drug development.

FDA told us about the guidance they had provided to the industry on ensuring clinical trials were inclusive, and the agency's willingness to consider novel clinical research methods. However, we also heard from patients who said that FDA's guidance was not doing enough to get results on the ground.

Given the length of time it often takes to diagnose ALS, many patients have found themselves locked out of clinical trials, despite the guidance urging developers to allow more flexible enrollment.

As a result, patients and their families are left to fight this devastating disease with very limited medical interventions. According to the patient advocates, FDA's guidance was not being implemented by developers and was not being followed by the agency itself. So H.R. 3537, the Accelerating Access to Critical Therapies for ALS Act, takes real steps to improve processes and activities at FDA to ensure patients can access clinical trials.

This legislation will help us get closer to effective cures and treatments for ALS. It requires FDA to develop and carry out an action plan to show how the agency will address ALS and other neurodegenerative diseases over the next 5 years.

The bill also creates a new grant program at FDA to cover research costs to characterize rare neurodegenerative diseases, identify molecular targets for the diseases, and increase efficiency and productivity of clinical trials.

Additionally, the bill creates a new grant program at the Department of Health and Human Services that will help pay for investigational drugs to prevent, diagnose, mitigate, treat, or cure ALS in expanded access programs. Expanded access is an important pathway for patients to receive experimental treatments, which should only be used when clinical trials and other effective treatments are not available.

Mr. Speaker, in committee, we ensured there would be a path forward for patients who are not able to participate in clinical research, but also clarified the intent and parameters of the program to maintain the scientific integrity of our research agencies.

The legislation now requires the Government Accountability Office to measure the program ahead of a 5-year sunset to ensure that these novel grant programs are benefiting patients and researchers. The grants included in this bill are charting new territory for NIH, and it is important we measure their level of success before we explore efforts to expand this program beyond ALS.

Mr. Speaker, this bill would not be here on the floor today were it not for the steadfast determination of patients and their families. At our hearing on this legislation in July, Brian Wallach and his wife, Sandra Abrevaya, cofounders of ''I Am ALS,'' spoke so eloquently of their own personal fight against ALS, and charged us with the task of passing this bill.

□ 1500

Hundreds of patient advocates across the country have made their voices heard to Members as well. To Brian, Sandra, and all the patients and their families, I reiterate what I said during our full committee markup: We heard you and now we are acting. We are grateful for your collaboration and willingness to work with us to improve this bill.

I also want to acknowledge the work of Representative MIKE QUIGLEY, the sponsor of this legislation, who has been tireless in his efforts to see this legislation across the finish line. I appreciate his willingness to work with us to get this bill to the committee so that it was ready for action here on the floor. I also want to thank our chairwoman of the Health Subcommittee, Ms. ESHOO, for all that she has done to move this bill.

Mr. Speaker, I urge my colleagues to support the ACT for ALS, and I reserve the balance of my time.

Mr. GUTHRIE. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I rise today in support of H.R. 3537, the Accelerating Access to Critical Therapies for ALS Act.

I am a proud cosponsor of this bill and want to thank Representatives FORTENBERRY and QUIGLEY for their tireless efforts to move this bill forward. We would not be here today without your hard work and the tremendous advocacy efforts of the ALS community, who have so passionately made the need for this legislation known to Congress.

ALS is a devastating neurodegenerative disease that affects nerve cells in the brain and spinal cord. Many people lose the ability to speak,

eat, move, and even breathe. Over 5,000 people are diagnosed with this disease each year, and the average life expectancy is only 2 to 5 years after diagnosis.

Recent years have brought a wealth of new scientific understanding regarding this disease. There are currently five drugs available to treat ALS, and while this is a remarkable achievement, we have more work ahead of us.

H.R. 3537 establishes a grant program through HHS to support research and access to investigational therapies to treat ALS for those patients who cannot access clinical trials. It also directs HHS to establish a public-private partnership for neurodegenerative diseases, which will advance the development and regulatory approval of drugs to help treat ALS and other rare neurodegenerative diseases.

This bill will ring hope to those with ALS and their loved ones by promoting access to potentially breakthrough treatments and help us to one day find a cure for this vicious disease.

Mr. Speaker, I urge my colleagues to support this bill, and I reserve the balance of my time.

Mr. PALLONE. Mr. Speaker, I yield 3 minutes to the gentleman from Illinois (Mr. QUIGLEY), the sponsor of the bill and the champion in the fight against ALS.

Mr. QUIGLEY. Mr. Speaker, everything is impossible; until it isn't. Nothing has a cure; until it does. Today, people diagnosed with ALS are expected to live between 2 to 5 years. During that time, they progressively lose their ability to use their limbs, to speak, to swallow, and ultimately to breathe. Being diagnosed with ALS is a death sentence; for now.

After my friend Brian Wallach was diagnosed with ALS an odds-defying 4 years ago, he made ending the disease the fight of his life. Not today, ALS, he frequently says, not today.

Mr. Speaker, ALS is not incurable; it is just that we have not fully committed to finding a cure yet. Not like Brian has, not like Brian's wife Sandra has, or the organization they founded, I AM ALS has.

ACT for ALS will give people living with ALS access to promising treatments and improve the research infrastructure we need to one day find the cure. Cruelly, up to 90 percent of people living with ALS are ineligible for clinical trials.

For people with such an aggressive disease to have neither an effective FDA-approached treatment nor access to promising drugs is a tragedy. ACT for ALS will correct this.

I would like to thank the 331 colleagues who have cosponsored this bill, Chairman PALLONE, Subcommittee Chairwoman ESHOO, and their staffs, for standing with the ALS community. I also want to extend a special thank you to Congressman FORTENBERRY, the colead on this bill, who has pursued our shared goal with relentless dedication. I thank my staff, Allison Jarus and David Steury, who have gone above and beyond in pursuit of this legislation.

This indeed is not a congressional achievement, it is an achievement of a community of advocates all around the country who are fighting for their lives, the lives of their loved ones, and the lives of everyone affected by ALS.

In addition to Brian and I AM ALS, I want to thank the Muscular Dystrophy Association and the ALS Association for their dedication. ALS may rob people of their physical ability to speak, but make no mistake, this community has made themselves heard. It is their will that has brought this vote to us today; it is their will, and with that will there is a way.

Where there is consensus, there can be progress. Where there is funding, a cure will follow. Today belongs to the tireless advocates, to the families of people with ALS, and to every American living with the disease.

Mr. Speaker, I urge a ''yes'' vote.

Mr. GUTHRIE. Mr. Speaker, I yield 2 minutes to the gentleman from Utah (Mr. CURTIS).

Mr. CURTIS. Mr. Speaker, I rise to share my support for expanding access for individuals to investigative drugs because I am concerned that we are not moving swiftly enough in order to prevent diagnosis, mitigate, treat, or cure ALS.

This is very personal to me, it is very personal to the committee. It hits extremely close to home for so many of us who have lost friends, and have seen good friends and neighbors struggle with their families with this difficult disease.

I had the opportunity to speak about this earlier today in the Energy and Commerce Committee hearing on biomedical innovation. We are not moving fast enough and we have more work to do.

Mr. Speaker, I applaud this Accelerating Access to Critical Therapies for ALS Act for working to create and further develop public-private partnerships and to prevent policies from being enacted that impede private sector investments and advancements.

Mr. Speaker, I urge my colleagues to support this bill.

Mr. PALLONE. Mr. Speaker, I yield 2 minutes to the gentlewomen from California (Ms. ESHOO), the chairwoman of the Health Subcommittee.

Ms. ESHOO. Mr. Speaker, I rise today in the strongest support of this legislation, Accelerating Access to Critical Therapies for ALS. It is called the ACT for ALS.

As chairwoman of the Health Subcommittee, I am so proud to have advanced this legislation which enjoys 331 bipartisan cosponsors, more than any other bill pending in the House. This legislation establishes grant programs to advance treatments for neurodegenerative diseases like ALS, allowing more patients to receive critical medicines through compassionate care programs.

Jamie Berry, one of my constituents, wrote a poignant letter to me, and said the following: ''With ALS, a piece of you dies every day. We are simply asking for a fighting chance to live the lives we were meant to live.'' As we gather here to pass this bill, Jamie is a patient in the neuro ICU unit at Stanford University Hospital.

Jamie, if you are listening, stay tuned, because your wish is going to come true today. To you, Jamie, and all your fellow ALS patients, I am proud that the United States House of Representatives will vote for this legislation to support your fighting chance against this deadly disease.

This is a transformational bill to make sure that people with ALS are given treatment options, and something they all deserve—it is spelled H-O-P-E, hope.

I salute Representatives QUIGLEY and FORTENBERRY, for the phenomenal job they have done on this legislation, both in introducing it and building it up to be the most cosponsored legislation in the House.

Mr. Speaker, I urge all my colleagues to support the bill, ACT for ALS.

Mr. GUTHRIE. Mr. Speaker, I yield 2 minutes to the gentleman from Louisiana (Mr. SCALISE), the distinguished Republican whip.

Mr. SCALISE. Mr. Speaker, I thank my friend from Kentucky (Mr. GUTHRIE) for yielding time.

Mr. Speaker, I want to first associate myself with the remarks made by Ms. ESHOO of California, as well as Mr. PALLONE, and stand up in strong support of this bill. I also thank the lead authors, Mr. FORTENBERRY and Mr. QUIGLEY, and all of us who have worked on this and other issues to help patients with ALS.

This goes back to other legislation that we have worked on, including the 21st Century Cures Act, where Congress came together, Republicans and Democrats, through the Energy and Commerce Committee, to help put a sharper focus on finding cures for diseases like ALS, diseases like Alzheimer's, and so many other debilitating diseases where you have got people that just want hope; as Ms. ESHOO said, where you have people who want the ability to live their lives to the fullest.

I know I have worked on so many of these ALS-related issues with a hero back home in my district, Steve Gleason. Steve Gleason was, for awhile, more famous as a player for the New Orleans Saints, somebody who gave us a light in the darkness of Hurricane Katrina, but then Steve was diagnosed with ALS. He turned his notoriety into a call for action for other people with ALS to be able to live their lives to the fullest.

Steve has been an inspiration to so many. He has a speech device that allows him to communicate; and he stays incredibly active. Steve brought this bill up over a year ago. So this is one more thing that we can do to help people with ALS; so that they can bring new therapies so that people living with ALS do have more ability to treat this disease.

This means lifesaving drugs will now be available for individuals who are not otherwise able to get into ALS clinical trials.

Mr. Speaker, on behalf of heroes, inspirational battlers like Steve Gleason, and so many of us have other heroes in our districts, I rise in strong support of this great piece of legislation that brings Republicans and Democrats together to take action for those people who are counting on us.

Mr. PALLONE. Mr. Speaker, I yield 2 minutes to the gentlewoman from Illinois (Ms. SCHAKOWSKY), the chairwoman of the Subcommittee on Consumer Protection and Commerce.

Ms. SCHAKOWSKY. Mr. Speaker, I thank the chairman of the Energy and Commerce Committee and the chair of the Health Subcommittee for this legislation.

Mr. Speaker, I rise today to remember my friend Artie. Artie and I were friends from the time we were in third grade in Chicago, and we stayed in touch all the many, many years. I was pretty devastated when he told me that he had ALS.

A couple of years ago Artie made the decision, because ALS is a really cruel disease, to take his own life, to set the date so that he would just make the decision himself and not suffer so horribly to the bitter end, because at that time he saw no hope.

Mr. Speaker, I rise today on behalf of my constituent, Brian Wallach and his wife, Sandra, who saw that there was hope in the future. They would fight in order to get legislation that would make access to what is promising therapies right now, therapies that weren't available or even on the horizon to Artie.

I am so proud to join with colleagues across the aisle to say that we can provide that hope, that opportunity to people who are facing what has been a death sentence, and that we can see a future that is bright for now the ALS victims.

Mr. Speaker, I want to thank I AM ALS, the organization, and many of the organizations that have been fighting for this. The advocates have done a great job to bring this to our attention and bring this day about and get over 300 cosponsors to this legislation. I am proud to be among them.

Mr. GUTHRIE. Mr. Speaker, as I mentioned, there are over 300 cosponsors, and we all know that is not an easy task to do at all. It takes a lot of work, a lot of leg work, a lot of effort. The two hardest working people that we have seen this session are Mr. QUIGLEY from Illinois, and my good friend JEFF FORTENBERRY from Nebraska, who put such effort into this.

Mr. Speaker, I yield 7 minutes to the gentleman from Nebraska (Mr. FORTENBERRY).

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Mr. FORTENBERRY. Mr. Speaker, I thank my friend, BRETT GUTHRIE, for his kind and generous words. It is very meaningful.

Mr. Speaker, one of the first books that I recall reading as a child was about the life of the famous New York Yankees first baseman named Lou Gehrig. He was nicknamed The Iron Horse due to his athletic ability and endurance. He could hit. He could run. He could field. He was an amazing athlete. And then, everything just changed. Amyotrophic lateral sclerosis stole that man's abilities, causing him to lose control of basic functions.

This merciless, cruel, and aggressive neurodegenerative condition mocked Lou Gehrig's famous durability. The disease became known as Lou Gehrig's disease, and today we call it ALS.

Mr. Speaker, there was no cure then, and there is no cure now.

Before he died in 1941, at a ceremony at home plate in Yankee Stadium, Lou Gehrig had this to say. He said: ''For the past 2 weeks, you have been reading about a bad break. Yet today, I consider myself the luckiest man on the face of the Earth.''

That story, Mr. Speaker, Lou Gehrig's story, stayed with me as a child. I don't know why, but it did, and I remember it so well.

Now, fast-forward decades later. While serving here as a Member of Congress, this same cruel disease has swept upon my own family.

I want to do this, Mr. Speaker, if you will indulge me. Pictured here is my wife, Celeste, with her little brother and godson, Joe Gregory. In his midthirties, Joe began to notice that his hand was shaking. He started a battery of tests, but somehow, he just knew it was probably going to be the worst of the worst. He was diagnosed with ALS, but he faced his plight with both dignity and courage. He volunteered to be a part of an experimental trial. He said: Well, if it doesn't work for me, maybe it will help someone else.

He died when he was 37 years old, and he left behind Melanie, his wife, and four little children. On his tombstone are the words from the prophet Isaiah: ''Here I am; send me.''

Mr. Speaker, as Joe began to die, we as a family quickly learned about this profound trauma that affects so many families all across America. It happens over and over out of view. Most of us never see it.

I soon became acquainted with this amazingly strong and determined ALS community. It was so uplifting to me to meet people filled with so much hope. You have heard that word over and over today, Mr. Speaker, and it is appropriate. So many people filled with so much hope amidst their own suffering but who rightfully sought a different approach and a better way.

Out of this experience was born the ACT for ALS.

Mr. Speaker, for over 50 years now and over 50 clinical trials, ALS patients have submitted themselves to tests, trials, therapies, and placebos in accordance with the rules of the current healthcare policy framework. But progress has been uneven, even debatable, with serious impediments to promising new treatments. Many have sacrificed their lives to science as they weakened and died.

But today, here we are, Mr. Speaker, with over 330 cosponsors from both sides of the aisle, and we are standing for a new way.

ACT for ALS represents a monumental shift in the way in which we approach ALS and other neurodegenerative diseases. At the core of this bill, it does two things. It transforms the paradigm of disease research and regulation, and it creates a new pathway for promising treatments. It drives the hope. With this groundbreaking law, we can break through faster for those who have suffered so much.

I want to publicly say thank you to Representative QUIGLEY for his tireless leadership in driving this hope, and my very close friends, Representatives ANNA ESHOO and CATHY MCMORRIS RODGERS, for their leadership in shepherding this bill as well. It is truly bipartisan. It was not easy, but here we are on the precipice of doing something good for so many people.

Mr. Speaker, I may be just a little bit like Lou Gehrig. I, too, am a lucky man, and for this reason: I have met so many beautiful people who have shared their sufferings, their vulnerability, and their gratitude toward this effort today. People of good heart, courageous, and who are fighters have created a family of solidarity to help us creatively rethink how to attack this disease through sound science, through technology, and through improved public policy.

Mr. Speaker, one last note: There are so many heroes who deserve special recognition, but you have heard one singled out today, and I want to single him out as well. This fight's Iron Horse is my friend and founder of the organization I AM ALS, Brian Wallach. As Brian said in congressional testimony in July with his wife, Sandra, there: ''This is our argument for our lives.''

Yes, it is, Brian.

So, Mr. Speaker, I should say publicly: Thank you, Brian; thank you, Joe; and thank you to the ALS community. We could not be here without you today.

Mr. GUTHRIE. Mr. Speaker, I yield myself the balance of my time to close.

Mr. Speaker, I would be remiss if I didn't mention a family as well.

Mr. Speaker, when you first come to Washington, you start getting to know people who come to advocate for diseases and treatments like this. I met the Ensor family. A lady named Kay Ensor came here with her 11- or 12-year-old daughter at the time, Shelby. Shelby came to my office and said:

I can't get a hug from my father anymore, and I don't want any other little girl to feel this way. It may be too late for us, but I don't want it to be too late for somebody in the future.

I got to know them, and I visited them in Lebanon Junction, Kentucky.

Their son, Tanner, was probably 8 or 9 at the time. They rigged up a wheelchair so he could go hunting with his father. But then it got to the point where they couldn't do that at all. Then, unfortunately, I was able to attend Mr. Ensor's funeral.

I don't have personal experiences in my family, but just seeing the effort that a family has to go through and the love that they do it in was an example for me to get involved in this issue, and the suffering that the patient goes through but also the extremely difficult circumstances for a family but how they were so loving in everything they did.

I want to close with this: I know that Brian and his wife, Sandra, were there at the hearing and touched every one of us. I want to yield back in honor of the Ensor family from Lebanon Junction, Kentucky, Mr. Speaker.

Mr. Speaker, I yield back the balance of my time.

Mr. PALLONE. Mr. Speaker, after listening to the personal stories on both sides of the aisle, I don't think anyone would question why this bill is important in order to provide hope to so many, as the speakers said, in order to try to find a cure and in order to try to find more treatments and clinical trials. All these are basically put into this legislation.

Mr. Speaker, again, I urge unanimous support for this bill on both sides, and I yield back the balance of my time.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from New Jersey (Mr. PALLONE) that the House suspend the rules and pass the bill, H.R. 3537, as amended.

The question was taken.

The SPEAKER pro tempore. In the opinion of the Chair, two-thirds being in the affirmative, the ayes have it.

Mr. WEBER of Texas. Mr. Speaker, on that I demand the yeas and nays.

The SPEAKER pro tempore. Pursuant to section 3(s) of House Resolution 8, the yeas and nays are ordered.

Pursuant to clause 8 of rule XX, further proceedings on this motion are postponed.

STILLBIRTH HEALTH IMPROVEMENT AND EDUCATION FOR AUTUMN ACT OF 2021

Mr. PALLONE. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 5487) to improve research and data collection on stillbirths, and for other purposes, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 5487

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Stillbirth Health Improvement and Education for Autumn Act of 2021'' or the ''SHINE for Autumn Act of 2021''.

SEC. 2. STILLBIRTH RESEARCH AND DATA COLLECTION IMPROVEMENTS.

Title III of the Public Health Service Act is amended by inserting after section 317L–1 of such Act (42 U.S.C. 247b–13a) the following:

''SEC. 317L–2. STILLBIRTH RESEARCH AND DATA COLLECTION IMPROVEMENTS.

''(a) STILLBIRTH SURVEILLANCE AND RISK FACTOR STUDIES.—

''(1) IN GENERAL.—The Secretary may award grants to States for purposes of—

''(A) conducting surveillance and collecting data with respect to stillbirths;

''(B) building State and local public health capacity to assess stillbirth data; and

''(C) collecting and reporting data on stillbirth risk factors, including any quantifiable outcomes with respect to such risk factors.

''(2) AUTHORIZATION OF APPROPRIATIONS.—To carry out this subsection, there is authorized to be appropriated $5,000,000 for each of fiscal years 2022 through 2026.

''(b) GUIDELINES AND EDUCATIONAL AWARENESS MATERIALS.—

''(1) IN GENERAL.—The Secretary shall—

''(A) issue guidelines to State departments of health and State and local vital statistics units on—

''(i) collecting data on stillbirth from health care providers, and with the consent of the family involved, including any such data with respect to the clinical history, postmortem examination, and placental pathology;

''(ii) sharing such data with Federal agencies determined appropriate by the Director of the Centers for Disease Control and Prevention; and

''(iii) improving processes and training related to stillbirth data collection and reporting to ensure standardization and completeness of data; and

''(B) develop, and make publicly available, educational awareness materials on stillbirths.

''(2) CONSULTATION.—In carrying out paragraph (1), the Secretary may consult with—

''(A) national health care professional associations;

''(B) national associations representing State and local public health officials;

''(C) organizations that assist families with burial support and bereavement services;

''(D) nurses and nurse practitioners;

''(E) obstetricians and gynecologists;

''(F) pediatricians;

''(G) maternal-fetal medicine specialists;

''(H) midwives;

''(I) mental health professionals;

''(J) statisticians;

''(K) individuals who have experienced a stillbirth; and

''(L) advocacy organizations representing such individuals.

''(3) AUTHORIZATION OF APPROPRIATIONS.—To carry out this subsection, there is authorized to be appropriated $1,000,000 for each of fiscal years 2022 through 2026.

''(c) VITAL STATISTICS UNIT DEFINED.—In this section, the term 'vital statistics unit' means the entity that is responsible for maintaining vital records for a State, or a political subdivision of such State, including official records of live births, deaths, fetal deaths, marriages, divorces, and annulments.''.

SEC. 3. PERINATAL PATHOLOGY FELLOWSHIPS.

The Public Health Service Act is amended by inserting after section 1122 of such Act (42 U.S.C. 300c–12) the following:

''SEC. 1123. IMPROVING PERINATAL PATHOLOGY.

''(a) IN GENERAL.—The Secretary shall establish and implement, or incorporate into an existing training program, a Perinatal Pathology Fellowship Program or a Postdoctoral Research Fellowship on Factors Associated with Stillbirth Program to—

''(1) provide training in perinatal autopsy pathology;

''(2) conduct research on, and improve data collection through fetal autopsies with respect to, stillbirth; and

''(3) address challenges in stillbirth education, research, and data collection.

''(b) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $3,000,000 for each of fiscal years 2022 through 2026.''.

SEC. 4. REPORTS.

(a) EDUCATIONAL GUIDELINES REPORT.—

(1) IN GENERAL.—Not later than five years after the date of enactment of this Act, the Secretary of Health and Human Services shall publish on a public website of the Department of Health and Human Services a report with educational guidelines on stillbirth and stillbirth risk factors.

(2) CONTENTS.—Such report shall include, to the extent practicable and appropriate, the guidelines issued and educational awareness materials developed under section 317L–2 of the Public Health Service Act, as added by section 2 of this Act.

(b) PROGRESS REPORT.—Not later than five years after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to the Congress a comprehensive report on the progress and effectiveness of the Perinatal Pathology Fellowship Program established under section 1123 of the Public Health Service Act, as added by section 3 of this Act.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from New Jersey (Mr. PALLONE) and the gentleman from Kentucky (Mr. GUTHRIE) each will control 20 minutes.

The Chair recognizes the gentleman from New Jersey.

GENERAL LEAVE

Mr. PALLONE. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days in which to revise and extend their remarks and include extraneous material on H.R. 5487.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from New Jersey?

There was no objection.

Mr. PALLONE. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, stillbirth is one of the most devastating losses that affects more than 24,000 families each year. Stillbirth touches families of all races, religions, and socioeconomic status.

For many parents, stillbirth is a loss that hits unexpectedly. In fact, up to half of all stillbirths occur in pregnancies that had seemed problem-free. However, miscarriages and stillbirths are not systematically recorded, even in developed countries, suggesting that the numbers could be even higher.

While there has been some progress in reducing stillbirths, causes and risk factors have not been explored extensively.

H.R. 5487, the SHINE for Autumn Act of 2021, is an important first step in promoting positive change around this issue. The legislation is in honor of Autumn Joy, who was born stillborn on July 8, 2011. For the last decade, her mother, Debbie Haine, has transformed her loss into action.

The legislation seeks to bolster research on stillbirths and stillbirth risk factors to lower our Nation's stillbirth rate. H.R. 5487 would provide resources to State and Federal health departments, improve data collection around stillbirths, and increase education and awareness.

Since a stillbirth is such a private, devastating life event, the data collected is only intended for the purpose